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K013201 1/4

510(k) SUMMARY FOR CARDIOFOCUS DIODE LASER SYSTEM

Submitter's Name, Address, Telephone Number, and Contact Person:

CardioFocus
Norton Commerce Center
10 Commerce Way
Norton, MA 02766

Contact: Joe Curtis
Phone: (508) 285-1700
Fax: (508) 285-7579
Email: joec@cardiofocus.com

Name of Device:

CardioFocus Laser System.

Common or Usual Name:

Surgical Laser Instrument

Classification Name:

Laser, Powered, Surgical Instrument.
CFR ref: 878.4810, product Code GEX

Predicate Devices:

Ceralas Diode Laser System
CeramOptec, Inc., East Longmeadow, MA
K001975; S.E. 8-4-2000

Intended Use:

The CardioFocus Laser Diode System is intended for the delivery of 980nm laser light to soft tissue in contact or non-contact mode during surgical procedures including via endoscopes, introducers or catheters. Indications include the incision, excision, dissection, vaporization, ablation or coagulation of soft tissue.

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General Description:

The CardioFocus Diode Laser Ablation System is a generator designed for the delivery of 980nm laser light and may be used in conjunction with surgical treatment for hemostasis, incision, ablation, coagulation and vaporization of tissue as required by the clinician. The instrument includes a diode laser module as the therapeutic energy source, as well as an internal thermal safety system for monitoring and disabling laser power output.

Device Characteristics:

The CardioFocus Laser Diode System is provided in two Models. The Model 30NR provides up to 30 watts, laser light and the Model 60NR provides up to 60 watts, laser light., The CardioFocus Diode Laser System may be used with the CardioFocus Lightstic 180L or Lightstic 180C delivery catheter (REF: 510K# K993834 and K011988), and successor delivery catheters from CardioFocus, Inc.

System safety characteristic are assured through conformance with applicable U.S. and International standards, including :

- UL 2601-1 Medical Electrical Equipment PART 1: General Requirements For Safety, Medical Electrical Equipment
- IEC 60601-2-22 Medical Electrical Equipment PART2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- IEC 60825-1 Safety of laser products - Part 1: Equipment classification, requirements and user's guide
- IEC 60601-1-2 (EN 60601-1-2) General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility
- IEC 1000 Electromagnetic Compatibility
- 21 CFR 1040.10/.11 Performance Standard for Light Emitting Products

Technical Characteristics

- System Controller: the system controller represents the hardware and software that monitors and controls the functioning of the laser instrument.
- Thermal Safety System (TSS): the thermal safety system is a safety circuit, intended to monitor the black body radiation associated with excessive heating in the disposable device and associated optics and to disable the laser in the event that excessive black body radiation is detected.
- Optics Module: the optics module is an optical sub-system which provides means for delivering laser energy and collecting white light energy from the delivery device and also provides means for directing black body radiation from the disposable device to the safety system IR detector.
- User Interface: the user interface provides means for information display to the user as well as a mechanism for user input. The user interface for the laser instrument will likely include an LCD display and a keypad.
- Foot Switch: the laser instrument will interface to a foot switch for on/off control of the laser emission.
- Diode Driver: the diode driver block represents the electronics required to control power supplied to the laser module
- Diode Module: the diode module is a purchased component, comprised of a series of laser diodes, which produces the output laser energy.
- Power Supply: an AC/DC power supply provides DC power necessary to run the system electronic components. The supply is internal to the laser instrument.

Predicate information is support of Substantial equivalence

The CardioFocus Diode Laser System is substantially equivalent to the CeramOptec Celaras D25 Fiber-Coupled Diode Laser System. Both devices provide laser energy at similar power levels and similar wavelengths, have similar intended uses and provide for safety though conformance to recognized standards.

Conclusion

There are more similarities than differences between the predicate device and the CardioFocus Diode laser System. Both the predicate devices use the same technology and theory of operation. Both the CardioFocus Laser System and the Ceralas Diode laser System use three configurations for different power levels and both devices have similar Indications for Use When used in accordance with the directions for use, by qualified personnel, the CardioFocus Diode Laser System is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2002

CardioFocus, Inc.
c/o Mr. John Greenbaum
Generic Devices Consulting
20310 SW 48th Street
Ft. Lauderdale, FL 33332

Re: K013201
Trade/Device Name: CardioFocus Diode Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k)Number(if known): K013201

Device Name: CardioFocus Diode Laser System

Indications For Use:

The CardioFocus Diode Laser System is intended for the delivery of 980nm laser light to soft tissue in contact or non-contact mode during surgical procedures including via endoscopes, introducers or catheters. Indications include the incision, excision, dissection, vaporization, ablation or coagulation of soft tissue.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013201

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

(Optional Format 1-2-96)